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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,271	05/04/2001	Steven M. Ruben	PF526	7683

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,271	RUBEN ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to nucleic acids, vectors, host cells and method for making protein recombinantly, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example.

II. Claim 20, drawn to polypeptides, classified in class 530, subclass 350, for example.

III. Claims 21 and 22, drawn to antibodies to the polypeptides of Group II, classified in class 530, subclass 388.22, for example.

IV. Claims 23, 25, 31 and 32, in so far as they are drawn to a method of treatment by administration of the polypeptides of Group II, classified in class 514, subclass 12, for example.

V. Claims 23, 27 and 29-32, in so far as they are drawn to a method of treatment by administration of antibodies of Group III, classified in class 514, subclass 2, for example.

VI. Claims 24 and 26, in so far as they are drawn to a method of diagnosis comprising contacting the polypeptides of Group II with a biological sample and assaying for binding, classified in class 436, subclass 501, for example.

VII. Claims 24 and 28, in so far as they are drawn to a method of diagnosis comprising contacting the antibodies of Group III with a biological sample and assaying for binding, classified in class 436, subclass 501, for example.

The inventions are distinct, each from the other because of the following reasons:

The polynucleotides of invention I are related to the polypeptides of invention II by virtue of encoding the same. The polynucleotides have utility for the recombinant production of the protein in a host cell. Although the polynucleotides and proteins are related since the polynucleotides encode the specifically claimed proteins, they are distinct inventions because the protein products can be made by another materially different process, such as by synthesis or purification from the natural source. Further, the polynucleotides may be used for processes other than the production of the proteins, such as nucleic acid hybridization assays.

The proteins of invention II are related to the antibodies of invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural receptor of the protein.

Invention I and each of inventions III, IV, V, VI and VII are related as a process of making and a process of using a common product. The polynucleotides of invention I encode the polypeptides, which are used in the methods of treatment with the polypeptides of invention

IV or the methods of diagnosis of invention VI, and which polypeptides are the cognate antigens necessary for production of the antibodies of invention III which are used in the method of treatment of invention V and the method of diagnosis of invention VII, but the polynucleotides may also be used as probes in a method of hybridization, which are materially different methods. The processes are patentably distinct because of different starting and ending points, method steps and goals.

Invention II is related to each of inventions IV and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in the method of treatment of invention IV, but the polypeptides can also be used in a method of diagnosis of invention VI, which is a materially different method, having different methods steps and goals.

Invention III is also related to each of inventions V and VII as product and process of use. In the instant case the antibodies can be used in the method of treatment of invention V, but the antibodies can also be used in a method of diagnosis of invention VII, which is a materially different method, having different methods steps and goals.

Invention II is unrelated to each of inventions V and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of invention II are not used or defined in the methods of treatment or diagnosis with the antibodies of inventions V and VII.

Invention III is unrelated to each of inventions IV and VI. In the instant case the antibodies of invention III are not used or defined in the methods of treatment with the polypeptides of inventions IV and VI.

Inventions IV and V are each unrelated to the other. Though both of the inventions are methods of treatment, the compounds that are administered (polypeptide or antibody) are different from each other, have different structures, functions and therapeutic effects, and thus are patentably distinct.

Inventions VI and VII are each unrelated to the other. Though both of the inventions are methods of diagnosis by contacting a biological sample with a compound and assaying for binding, the compounds that are used in the binding assays (polypeptide or antibody) are different biological molecules that have different structures, functions and bind to different molecules in the biological sample, and thus are patentably distinct.

Inventions IV and V are unrelated to inventions VI and VII. The two groups of inventions are different because inventions IV and V are methods of treatment, while inventions VI and VII are methods of diagnosis by contacting a biological sample, and thus have different methods steps and goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election for Groups IV-VII

If one of Groups IV-VII is elected, Applicant is further required to elect a species. This application contains claims directed to the following patentably distinct species of the claimed invention:

A) an immunodeficiency or condition associated with an immunodeficiency, or

B) an autoimmune disease or condition associated with an autoimmune disease.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

If A is elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of immunodeficiency from those listed in claims 23 and 24 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 29 and 30 are generic.

If B is elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of autoimmune disease from those listed in claims 25-28 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 31 and 32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1646